Specifically, the Examiner states that Gleichenhagen et al teaches a sprayable polymer composition for formation of a film over a wound area using solvents, such as ethyl acetate, acetone, or ethanol (see column 1, lines 33-65 thereof). Furthermore, the Examiner states that such films contain polymers, such as acrylic acid and methacrylic acid, as well as softeners (plasticizers) such as phthalates (see column 1, lines 45-48 thereof). Further, the Examiner states that Gleichenhagen et al teaches the use of additional antiseptic or bacteriostatic substances (see column 6, lines 65 to column 7, line 2). The Examiner notes that Gleichenhagen et al does not teach the concentration of the components of the present application. However, the Examiner contends that in the absence of unexpected results, such would have been obvious.

The Examiner further states that Tipton et al teaches a biodegradable film dressing and an apparatus for the spray delivery of the dressing, which can be used to protect and promote healing of injured tissue and to deliver biologically active agents. Further, the Examiner states that Tipton et al uses solvents such as acetone, a water-soluble pore-forming agent, as well as an antifungal agent and phthalic esters as modifiers.

In addition, the Examiner states that Modak et al teaches a method of inactivating irritants in a fluid contacting skin comprising applying a composition to the skin where the active anti-irritants include cetrimide, chlorbutanol and triclosan.

Hence, the Examiner concludes that it would have been obvious to modify the compositions of Gleichenhagen et al to use

the active agents taught in Tipton et al and Modak et al to achieve the present invention.

For the following reasons, Applicant respectfully traverses the Examiner's rejection.

Gleichenhagen et al deals with the problems associated with film-forming polymers which can be sprayed onto the skin to form wound bandages. These problems are set out at column 2, line 18 through column 3, line 41 thereof. The problems include discoloration during production (column 3, line 15), brittleness and easy tearing (column 3, line 16), allergic reactions (column 2, line 24), unpleasant smell (column 3, line 31), lack of optical clarity (column 3, line 31) and lack of solubility in organic solvents-propellant mixtures (column 3, lines 35-36).

The solution to the above-noted problems of sprayable compositions solved in Gleichenhagen et al are said to be "suprisingly...obtained" by use of a mixed polymeride, particularly based on mixed polymerization of isobutene with lower acrylic or methacrylic acid esters and malic monoesters (see column 3, lines 53-62, and Claim 1 thereof). The polymers of Gleichenhagen et al are soluble in an organic solvent (see column 5, lines 38-41), and the concentrated polymeric/organic solvent solution is mixed with liquified propellant gas (e.g., a halogen hydrocarbon), and optionally blood coagulating antiseptic bacteriostatic substances (see column 6, last two lines through column 7, first two lines).

On the other hand, the present invention relates to a non-aerosol sprayable skin patch composition.

Further, it is apparent from the above-noted disclosure in Gleichenhagen et al that the optional blood coagulating antiseptic or bacteriostatic agent must be soluble in the organic solvent in order to overcome one of the problems of the prior art identified in Gleichenhagen et al, i.e., lack of solubility of the components (see column 3, lines 31-39).

On the other hand, in the present invention, the physiologically active ingredient(s) employed are water-soluble.

In addition, the composition of Gleichenhagen et al is described as being a film-forming, sprayable, stable solution which does not require softening agents or plasticizers (see column 3, lines 42 through line 52).

On the other hand, the composition of the present invention contains a plasticizer.

Applicant respectfully submits that the Examiner, at page 2 of the Office Action, has mischaracterized the teachings of Gleichenhagen et al insofar as the Examiner refers to the teachings of Gleichenhagen et al at column 1. The teachings at column 1 and 2 of Gleichenhagen et al represent the prior art which is said to be disadvantageous and suffer from numerous disadvantages which Gleichenhagen et al seeks to solve by a specific polymer combination and an organic solvent.

Accordingly, Applicant respectfully submits that the present invention is not taught or suggested in Gleichenhagen et al, and for the following reasons, it is clear that Tipton et al and Modak et al do not provide the deficiencies that exist therein.

Tipton et al teaches compositions and methods which are very different from those of Gleichenhagen et al, let alone those of the present invention.

Tipton et al relates to a two-part composition, wherein a thermoplastic polymer, with an optional bioactive agent in an organic solvent, is applied to skin, and then contacted with an aqueous based fluid to coagulate or solidify the film onto the human animal or tissue (see column 3, line 57 to column 4, line 9). The thermoplastic polymer of Tipton et al is substantially insoluble in the aqueous fluid, giving rise to coagulation and film formation. This is entirely different from the present invention which is a one-step composition.

The mechanism of delivery of the water-soluble compound (e.g., peptide) in the present invention is taught at page 6, lines 19-34 of the present specification. There is no water in the film of the present invention, in distinct contrast to Tipton et al. However, when the film of the present invention comes into contact with moisture on the skin, the water-soluble material can leach out of the film.

Applicants previously amended the claims to recite "consisting essentially of" to, *inter alia*, exclude the presence of water, which is disadvantageous to creating the film of the present invention.

Tipton et al therefore teaches compositions and methods which are very different from those claimed in the instant invention.

Hence, one skilled in the art would not have been motivated to combine the teachings of Gleichenhagen et al with

Tipton et al because the one part composition of Gleichenhagen et al is completely different from the two part composition of Tipton et al.

Moreover, one skilled in the art would not have been motivated to combine the teachings of Gleichenhagen et al with Modak et al.

Modak et al is entirely different from composition of Gleichenhagen et al and the present invention, as it relates to a gel. A gel is not sprayable. One skilled in the art would clearly not have been motivated to combine the gel teachings of Modak et al with Tipton et al and Gleichenhagen et al to achieve a non-aerosol sprayable skin patch composition, as claimed in the present invention.

Furthermore, Modak et al does not teach or suggest progressive disintegration over a 24 to 48 hour time period, as claimed in the present application.

Finally, one person skilled in the art would clearly not have been motivated to combine the specific polymer teachings of Gleichenhagen et al with the gel teachings of Modak et al, and the two part water containing the composition of Tipton et al, to achieve the present invention.

Applicants respectfully submit that the Examiner's obviousness rejection improperly relies on hindsight, and that there would have been no motivation to one of ordinary skill in the art to combine the teachings of Gleichenhagen et al with Tipton et al and/or Modak et al to achieve the present invention.

Accordingly, Applicant respectfully submits that the present invention is not taught or suggested in Gleichenhagen et al, alone or when combined with the teaching of Tipton et al and Modak et al, and thus requests withdrawal of the Examiner's rejection.

In view of the arguments set forth above, reexamination, reconsideration, and allowance are requested.

The Examiner is invited to contact the undersigned at his Washington telephone number on any questions which might arise.

Respectfully submitted,

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